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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/647,458

08/01/2003

Sophie Chen

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

06/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No. 10/647,458	Applicant(s) CHEN, SOPHIE	
	Examiner CHRIS E. SIMMONS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,19,21-23,26-29,32,33,35,36,38,39 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) 52-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,19,21-23,26-29,32,33,35,36,38,39 and 44-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/06/2003, 11/14/2003, 02/09/2004, 04/12/2004,</u> | 6) <input type="checkbox"/> Other: ____. |
| <u>09/30/2004, 12/19/2005.</u> | |

DETAILED ACTION

Applicants' arguments, filed 03/16/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

Newly submitted claim 52-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: applicant has constructively elected *Ganoderma luciderma* as the stimulant when it was specifically claimed as the only possible immune stimulant in claim 51 where applicant has received an Office action rejecting the specific stimulant. Since applicant has received an action on the merits for this presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 52-59 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1, 2, 5-7, 19, 21-23, 26-29, 32, 33, 35, 36, 38, 39 and 44-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It does not appear that there is adequate written description for the term "consisting essentially of". Applicant refers to instant paragraphs [0066] and [0067] as support for the limitation but it is not apparent from the disclosure that there is support as alleged. The limitation is considered to introduce new matter.

Inadequate Written Description

Claims 1, 2, 5-7, 19, 21-23, 26-29, 32, 33, 35, 36, 38, 39 and 44-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The term "consisting essentially" is inadequately described by the instant specification since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a

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given ingredient “materially affects the basic or novel characteristics of the invention”.

Obviousness Rejections

Claims 1-2, 5-7, 19, 20-23, 26-29, 32, 34-36, 38 and 39 stand rejected under 35 USC 103(a) as being unpatentable over JP-09-176011 in view of USP 6,498,188.

Applicant argues that the JP reference does not show treatment in humans and therefore, does not suggest treatment in humans. This is not persuasive because the JP reference discloses positive results showing anticancer effectiveness of human cancer cells. It would, therefore, be obvious to eventually upgrade the study/treatment into animals, including humans.

Applicant further argues that wogonin is not used to treat cancer per se but is used to control HSP 27 expression. This is not persuasive because the reference clearly suggests that such control of HSP 27 results in effectiveness cancer treatment. Applicant admits that the reference wogonin is disclosed to “reinforce the effectiveness of chemotherapy”. The examiner believes this corroborates the examiner’s position that the reference does suggest treatment of cancer using wogonin to at *least* “reinforce” chemotherapy. The examiner further submits that to “reinforce the effectiveness of chemotherapy” comprises treatment of cancer.

Applicant further criticizes the secondary reference alleging that it does not disclose combination therapy and further alleges the reference only discloses that carbamates and thiocarbamates kill cells.

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As for the unexpected results, alleged by applicant, the examiner notes that there is no proper showing of unexpected results. There is no side-by-side comparison of unexpected data. In the case that applicant did show unexpected results, purely in arguendo, the results demonstrated in TABLE 3 only shows effects on PSA - which is not commensurate in scope with the pending claims.

As for the "consisting essentially of" limitation, it is submitted that since the instant specification fails to contemplate the exclusion of any particular ingredients as implied therein and does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention", the limitation when given its broadest reasonably interpretation reads as broad comprising language.

Claims 1-2, 5-6, 19, 20, 22, 23, 26, 29, 32, 34, 36 and 38 stand rejected under 35 USC 103(a) as being unpatentable over JP-09-176011 in view of USP 6,413,535.

Applicant argues that the secondary reference does not teach wogonin but acknowledged that the references the reference is directed to chemoprevention of prostate cancer using phytoestrogens and other anti-cancer agents. In response to applicant's arguments against the reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In this case, any alleged shortcoming of one reference is remedied by the other.

Applicant again relies on assertions of unexpected results and “consisting essentially of” language. These assertions are not found to be persuasive. The examiner refers to his remarks above regarding these issues.

Claims 21, 27, 35, 39, 50 and 51 are rejected under 35 USC 103(a) as being unpatentable over JP 09-176011 and USP 6,413,535 in view of JP 11-244597.

Applicant argues that JP ‘597 does not remedy the defects of the primary and secondary references and relies on above arguments. The examiner does not find the arguments to be persuasive for reasons set forth above.

Claims 1-2, 5-7, 19, 20-23, 26-29, 32-36, 38, 39, and 46-51 stand rejected under 35 USC 103(a) as being unpatentable over USP 5,665,393.

Applicant argues that the examiner has not provided an explanation of the substance of the rejection. The examiner disagrees. This reference was outlined in connection with its PCT publication, WO 98/09615 (*infra*). The examiner refers to page 7 of the 10/14/2008 Office action where it is explicitly stated that “[b]oth references (USP 5,665,393 and WO 98/09615) disclose herbal compositions for treating prostate cancer...”. It is clear that both references were discussed together.

Applicant also argues that the composition of the US patent contain ingredients that are not in the present composition. This is not persuasive because the “consisting essentially of” limitation is broad as outlined *supra*.

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Applicant argues that the amounts of wogonin are different between the present invention and the prior art because the extraction technique used in the prior art renders lower amounts. As support, applicant first asserts that the purification technique used for the purified wogonin was using the method described in the instant prior art and refers to instant Fig. 3 which shows mass spectrum data of purified wogonin. Firstly, there is nothing of record that refers to purification techniques of the instant prior art other than the unsupported assertion currently made. Secondly, even if the amount of wogonin in the prior art is lower than the amount currently claimed, it is still obvious to increase the amount of the *Scutellaria baicalensis* (which contains wogonin) in order to increase its anti-cancer effects. By increasing the amount of *S. baicalensis*, one would also naturally increase the amount of wogonin in the composition.

Claims 1-2, 5-7, 19, 20-23, 26-29, 32-36, 38, 39, and 46-51 stand rejected under 35 USC 103(a) as being unpatentable over WO 98/09615.

This is the PCT publication for USP 5,665,393 (above). Applicant relies on arguments above. Examiner relies on his response to applicant's arguments above.

Claims 44 and 45 are rejected under 35 USC 103(a) as being unpatentable over US 2002/0182274.

Applicant asserts that the reference does not disclose wogonin. The

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examiner disagrees because *Scutellaria baicalensis* Georgi, which contains wogonin, is disclosed in the reference [0046]. Applicant argues that, if a cancer is resistant to one anti-cancer agent, then it would often be resistant to multiple agents. Applicant argues that taxol-resistant cancer is much more difficult to treat non-resistant cancer. Because of this, according to applicant, one of ordinary skill in the art would not be motivated to use another known anti-cancer agent. The examiner disagrees. As applicant has acknowledged, the reference discloses treatment of ovarian cancer. Although, taxol-resistant ovarian cancer may be more difficult to treat than non-resistant ovarian cancer, it is submitted that, generally, if a cancer develops resistance to a drug, it is necessary to switch to a second drug to circumvent this resistance, especially to a drug known to treat that cancer. In this case, as applicant acknowledges, the prior art discloses treatments for ovarian cancer, if the ovarian cancer is taxol resistant, then it would be necessary to switch to another composition known to treat ovarian cancer.

Applicant request a complete explanation if this rejection is maintained. It appears applicant believed that wogonin was not present in the reference. However, the examiner explained in the 10/14/2008 Office action that fermented extract of Chinese herbs such as *Scutellaria baicalensis* Georgi, which contains wogonin, is an agent disclosed for use in the anti-cancer compositions of the reference at [0046]. Applicant can find the complete explanation in the prior 10/14/2008 Office action which states.

No claims are allowed.

Double Patenting

Claims 1-2, 5-7, 19, 20-23, 26-29, 32-36, 38, 39, and 46-51 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 5,665,393.

Applicant relies on arguments relying on limitations alleged by using “consisting essentially of”. For reasons outlined above, the arguments are not found to be persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

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/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612